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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,864	01/16/2004	Erik H.F. Wong	30744/6248.11	1198

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EXAMINER

SPIVACK, PHYLLIS G

ART UNIT PAPER NUMBER

1614

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/758,864

Applicant(s)

WONG ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 32-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                        |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____   |

Applicants' Preliminary Amendment filed January 16, 2004 is acknowledged.

Claims 18-31 and 41-53 are canceled. Claims 1-17 and 32-40 are pending.

Information Disclosure Statements filed January 16, 2004, August 30, 2004 and September 10, 2004 are acknowledged. The references have been reviewed to the extent each is a proper citation on a U.S. patent.

A new title and updated priority information are noted.

The abstract of the disclosure is objected to because the present claims are not directed to compositions. Correction is required. See MPEP § 608.01(b).

In response to a request for an election of species, (S,S) reboxetine was elected. Accordingly, the subject matter under consideration are those methods of treatment comprising administering (S,S) reboxetine to treat peripheral neuropathy, claims 1-17 and 32-40.

Claims 1-17 and 32-40 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or practice the invention. The claims are directed to the treatment or prevention of peripheral neuropathy. The specification provides a review of various pathologies that are known in the prior art to respond to treatment with reboxetine. The specification provides support for the ability of reboxetine as a racemic mixture, as (S,S) reboxetine and (R,R) reboxetine to bind to norepinephrine and serotonin reuptake sites using two radioligands in the Table on page 31. The specification provides no support for treating or preventing peripheral neuropathy and,

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optionally, diminishing adverse side effects comprising administering any compound having a pharmacological selectivity of serotonin(ki)/norepinephrine (Ki) of at least about 5000.

Undue experimentation would be required to practice the claimed methods of use as they are presented.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 where the court set forth factors to consider when assessing whether or not a disclosure would require undue experimentation. These factors are:

- 1) the quantity of experimentation necessary
- 2) the amount of direction or guidance provided
- 3) the presence or absence of working examples
- 4) the nature of the invention
- 5) the state of the art
- 6) the relative skill of those in the art
- 7) the predictability of the art and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan background sufficient to practice the instant invention without resorting to undue experimentation in view of further discussion below.

The nature of the invention, state of the prior art, relative skill of those in the art and the predictability of the art

The claimed invention relates to prevention or treatment of peripheral neuropathy, while optionally diminishing adverse side effects comprising administering (S,S) reboxetine.

The relative skill of those in the art is generally that of a Ph.D. or M.D. with expertise in the area of neurology.

The prior art does not presently recognize methods of preventing peripheral neuropathy or means of diminishing the side effects of reboxetine therapy. Because this particular art is immature, a more detailed description as to the means of practicing the claimed methods would reasonably be expected.

The breadth of the claims

Claim 39 is broad in that the number and type of adverse side effects are substantial.

The amount of direction or guidance provided and the presence or absence of working examples

There are no working examples directed to the treatment or prevention of peripheral neuropathy. There are no examples to support or suggest a successful therapeutic regimen.

The quantity of experimentation necessary

Applicants have failed to provide support for efficacy in the treatment or prevention of peripheral neuropathy, and diminishing adverse side effects following the administration of (S,S) reboxetine. The skilled artisan would expect the interaction of a particular compound in the prevention or treatment of this particular neurological

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disorder to be very specific and highly unpredictable absent a clear understanding of the structural and biochemical basis for the administration of a particular compound. The instant specification sets forth no such understanding. No direction is provided to distinguish therapy among the various adverse effects. Absent reasonable *a priori* expectations of success for preventing any peripheral neuropathy and diminishing adverse effects, one skilled in the art would have to test extensively many adverse outcomes of therapy to discover which particular side effects respond to (S,S) reboxetine therapy. Since each prospective embodiment, as well as future embodiments as the art progresses, would have to be empirically tested, undue experimentation would be required to practice the invention as it is claimed in its current scope. The specification provides inadequate guidance to do otherwise.

No claim is allowed.

Dostert et al., European Neuropsychopharmacology, is cited to show the greater potency noted in the (S,S) enantiomer of reboxetine.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The Examiner can normally be reached from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached 571-272-951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

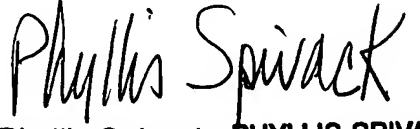
Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

October 16, 2005

  
Phyllis Spivack **PHYLLIS SPIVACK**  
**PRIMARY EXAMINER**

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